K042130

SEP - 8 2004

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Suite 205
Minneapolis, MN 55414
Ph: 612-455-0550
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Summary of Safety and Effectiveness

Company Name: AEIOMed, Inc.
1313 5th Street SE, Suite 205
Minneapolis, MN 55414

Contact: Dave Markovich, Senior Director of Operations

Phone: (612) 455-0550

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Summary Date: August 4, 2004

Trade Name: Aura™ CPAP Patient Interface

Common Name: CPAP Accessory: Nasal CPAP Mask

Classification Name: 21 CFR 868.5905, Non-Continuous (Respirator) Ventilator

Predicate Devices:

510(k) Number: K022465
Manufacture: Innomed Technologies
Trade Name: Nasal-Aire II™

510(k) Number: K033759
Manufacture: Respironics, Inc.
Trade Name: ComfortLite™

1.0 Description of Device

The Aura™ CPAP Patient Interface is an accessory to continuous positive airway pressure (CPAP) devices, which are applied to treat Obstructive Sleep Apnea with CPAP or Bi-Level CPAP.

The Aura CPAP Patient Interface is initially used under the direct supervision of a trained medical professional. The Aura CPAP Patient Interface function and applications may be reviewed in a clinical setting when the patient is treated for obstructive sleep apnea by the application of CPAP therapy.

2.0 Intended Use

The Aura™ CPAP Patient Interface is an accessory to continuous positive airway pressure (CPAP) devices, which are applied to treat Obstructive Sleep Apnea with CPAP or Bi-Level CPAP therapy.

3.0 Technology

The Aura™ CPAP Patient Interface has three significant components:

1) Headgear Assembly,
2) Nasal Seal Assembly, and
3) Tubing and Adjustment Assembly.

The Headgear Assembly holds the device Tubing and Adjustment Assembly, and the Nasal Seal Assembly in place on the user's head. The Headgear Assembly is adjustable by the user.

The Nasal Seal Assembly is made from a silicone material which connects to the Tubing and Adjustment Assembly. The Nasal Seal Assembly provides the airflow pathway to the user's nasal openings.

The Tubing and Adjustment Assembly connects to the CPAP System. The Tubing and Adjustment Assembly passes the constant air pressure of the CPAP System to the Nasal Seal Assembly. The Tubing and Adjustment Assembly allows the positioning of the Nasal Seal Assembly for the comfort of the user. The Tubing and Adjustment Assembly allows for the positions of the Nasal Seal Assembly in both dimensions: away from the face and in the vertical direction.

4.0 Conclusions

The Aura™ CPAP Patient Interface is substantially equivalent to the predicate devices. Laboratory and standards compliance were provided to support the Aura™ CPAP Patient Interface. No new questions of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2004

AEIOMed, Incorporated
C/O Mr. Gary Syring
Quality & Regulatory Associates, LLC
800 Levanger Lane
Stoughton, Wisconsin 53589

Re: K042130
Trade/Device Name: Aura™ CPAP Patient Interface
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: August 4, 2004
Received: August 6, 2004

Dear Mr. Syring:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

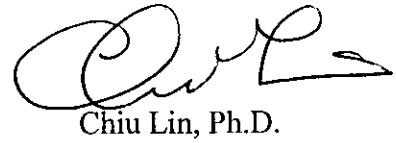
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Aura™ CPAP Patient Interface

Indications for Use:

The Aura™ CPAP Patient Interface is an accessory to continuous positive airway pressure (CPAP) devices, which are applied to treat Obstructive Sleep Apnea with CPAP or Bi-Level CPAP therapy.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K042130